

**K080989 UNIVERSAL VIAL ACCESS SPIKE**May 2, 2008  
25 days to decisionK080989 · Product code: **FMF** · General Hospital  
Source: <https://www.510kdatabase.net/k080989/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Syringe, Piston (FMF)
Date received	Apr 7, 2008
Decision date	May 2, 2008
Days to decision	25 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Icu Medical, Inc.</b>
Location	Walker, MI, US
Contact	TRACY BEST
510(k) history	66 submissions · 65 cleared · 1984-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k080989/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 25, 2026